K100985

510(k) Summary
21 CFR 807.92

SEP 09 2010

Submitter's Name & Address

Manufacturer: BioHorizons Implant Systems, Inc.
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Official contact: Michael Davis, Regulatory Affairs Specialist
Date prepared: August 12, 2010

Name of the Device

Trade Name: BioHorizons Simple Solutions with Laser-Lok®
Common or Usual Name: Dental implant abutment
Classification Name: Endosseous dental implant abutment
Classification Number: Class II (21 CFR 872.3630)

Predicate Devices

1. BioHorizons Single-stage Implant System, documented under 510(k) number K073282, concurrence date of February 15, 2008.
2. BioHorizons Internal Implant System, documented under 510(k) number K073268, concurrence date of February 8, 2008.
3. BioHorizons Tapered Internal Implant System, documented under 510(k) number K071638, concurrence date of October 10, 2007.
4. Zimmer Dental (formerly Sulzer Dental) ScrewVent and Tapered ScrewVent systems, documented under 510(k) number K013227, concurrence date of November 19, 2001.
5. BioHorizons Laser-Lok 3.0 Implant System, documented under K093321, concurrence date of April 2, 2010.

Device Description

BioHorizons Simple Solutions with Laser-Lok is an abutment system comprised of machined titanium endosseous dental implant healing abutments and final restorative abutments supplied in platform diameters of 3.5mm, 4.5mm and 5.7mm with collar heights of 0.8mm, 1.8mm and 2.8mm. Abutment material is titanium alloy as specified in ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy (UNS R56401) for Surgical Implant Applications.*

The devices are further processed by applying patterns of micro-machined grooves or channels, known as Laser-Lok, to a specified portion of the abutment margin. The product is packaged using materials known in the industry to be appropriate for medical device packaging and is provided with a minimum sterility assurance level of 10^{-6}, validated in compliance with ANSI/AAMI/ISO 11137-1 *Sterilization of healthcare products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices* and ANSI/AAMI/ISO 11137-2 *Sterilization of healthcare products – Radiation -- Part 2: Establishing the sterilization dose.*

Intended Use

BioHorizons Simple Solutions with Laser-Lok is an abutment system that includes healing abutments for contouring tissue and final restorative abutments for cementing a prosthesis. The abutment system may be used for a single or multiple unit restoration and is compatible for use with BioHorizons Internal and Tapered Internal implant systems and Zimmer Dental ScrewVent and Tapered ScrewVent implants with 3.5mm, 4.5mm and 5.7mm internal hex-connection mating platform diameters.

Compatibility Testing

Compatibility testing was performed on a representative subset of Zimmer ScrewVent and Tapered ScrewVent implants. The subset included the following Zimmer item numbers: TSVB8, TSV4B11, TSV4B13, TSVH13, TSV4H10, TSV4H11, TSV4H16, TSVWH10, TSVWH11, TSVWH13, TSVWH16, TSV6B8, TSV6H8, TSV6H10, TSV6H11 and TSV6H13. This testing verifies compatibility with all Zimmer ScrewVent and Tapered ScrewVent items listed in the following table based on equivalent mating platform geometry.

Platform	Zimmer Tapered ScrewVent Implants*	Zimmer ScrewVent Implants*	Simple Solutions Healing Abutments	Simple Solutions Abutments	
3.5mm Internal Connection	TSVBx TSV4Bx TSVHx TSV4Hx	SVMBx SVBx SVMHx SVHx	PYHA08L PYHA18L PYHA28L	PY4008L PY4018L PY4028L	PY5508L PY5518L PY5528L
4.5mm Internal Connection	TSVWBx TSVWHx	SVWBx SVWHx	PGHA08L PGHA18L PGHA28L	PG4008L PG4018L PG4028L	PG5508L PG5518L PG5528L
5.7mm Internal Connection	TSV6Bx TSV6Hx	N/A	PBHA08L PBHA18L PBHA28L	PB4008L PB4018L PB4028L	PB5508L PB5518L PB5528L

* Where variable x = implant length

Technological Characteristics

The fundamental scientific technology of the BioHorizons Simple Solutions with Laser-Lok is substantially equivalent to the existing abutments that are designed to mate with the implant components of the referenced predicate devices. The devices are further processed by applying Laser-Lok to a specified region of the abutment margin.

Laser-Lok is a surface feature in which patterns of micro-machined grooves are applied to the abutment margin, providing a roughened surface to establish a physical, connective tissue attachment (unlike Sharpey fiber attachment). This tissue connection:

1) is functionally oriented,
2) inhibits epithelial cell downgrowth and
3) enables crestal bone attachment adjacent to the implant.

All materials, suppliers, processing, packaging and sterilization methods remain the same as those utilized for the predicate BioHorizons implant systems (K073282, K073268 and K071638), and the Laser-Lok feature is substantially equivalent to that cleared for the BioHorizons Laser-Lok 3.0 Implant System (K093321). The BioHorizons Simple Solutions with Laser-Lok, which is the subject of this 510(k), is substantially

equivalent to all features of the predicate implant devices which could affect safety or effectiveness because of the similarities in design, materials and intended use.

Summary of Testing

The data presented in this 510(k) submission supports the substantial equivalence of the BioHorizons Simple Solutions with Laser-Lok to the specified predicate devices with respect to performance, safety and effectiveness. A prospective study was conducted in a canine model to evaluate bone and soft tissue healing patterns when Laser-Lok microgrooves are applied to dental implant abutments. The study consisted of four cohorts – Group A: Laser-Lok healing abutment on an RBT implant; Group B: Laser-Lok healing abutment on an RBT implant with a machined area; Group C: Machined healing abutment on an RBT implant; and Group D: Machined healing abutment on an RBT implant with a machined area. Laser-Lok and machined-surface healing abutments were randomly assigned to internal-connection implants that were either fully RBT-treated or RBT-treated with a 0.3mm machined collar. Each group received nine implants with abutments placed at the time of surgery. The results demonstrate significant improvement in peri-implant hard and soft tissue healing on the Laser-Lok healing abutments as compared to traditional machined abutment surfaces.

Nevins *et al* concluded that the presence of the 0.7-mm laser-ablated microchanneled zone consistently enabled intense fibroblastic activity to occur on the abutment-grooved surface, resulting in an interlacing complex of connective tissue fibers oriented perpendicular to the abutment surface that served as a physiologic barrier to apical JE migration.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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SEP 0 9 2010

Re: K100985
Trade/Device Name: Bio-Horizons Simple Solutions with Laser-Lok®
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: August 25, 2010
Received: August 30, 2010

Dear Mr. Davis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

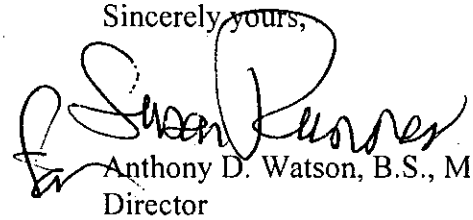
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
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Radiological Health

Enclosure

Indications for Use

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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